

FIGURE 1

Once-Weekly Eprex® Increases Hemoglobin and Decreases Ribavirin Dose Reductions Among HCV-Infected Patients Who Develop Anemia on Ribavirin/Interferon alpha-2b Therapy

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ABSTRACT

Background: Anemia is a major side effect of combination therapy for chronic hepatitis C virus (HCV) infection. Eprex® (epoetin alfa) is a recombinant erythropoietin that increases hemoglobin (Hb) levels. In a phase II study, Eprex® was compared with interferon (IFN) and ribavirin (RBV) in HCV-infected patients. The purpose of this study was to evaluate the effect of Eprex® on Hb levels and RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy.

Methods: In an ongoing, open-label, multicenter study, HCV-infected patients who develop anemia (Hb level ≤ 11.5 g/dL) on RBV therapy were randomized to receive Eprex® or placebo. The primary endpoint was the percentage of patients who required a RBV dose reduction. Secondary endpoints included Hb levels, Eprex® dose, and adverse events.

Results: Fifty-four patients were randomized to the Eprex® group and 54 to the placebo group. The Eprex® group had significantly higher Hb levels and fewer RBV dose reductions compared to the placebo group. Eprex® dose was also significantly higher in the Eprex® group.

Conclusions: Eprex® significantly increases Hb levels and decreases RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy. Eprex® is a safe and effective treatment for anemia in this population.

INTRODUCTION

Anemia is a major side effect of combination therapy for chronic hepatitis C virus (HCV) infection. Eprex® (epoetin alfa) is a recombinant erythropoietin that increases hemoglobin (Hb) levels. In a phase II study, Eprex® was compared with interferon (IFN) and ribavirin (RBV) in HCV-infected patients. The purpose of this study was to evaluate the effect of Eprex® on Hb levels and RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy.

STUDY OBJECTIVES

Determine the effect of Eprex® on Hb levels and RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy. Evaluate the safety and tolerability of Eprex® in this population.

METHODS

In an ongoing, open-label, multicenter study, HCV-infected patients who develop anemia (Hb level ≤ 11.5 g/dL) on RBV therapy were randomized to receive Eprex® or placebo. The primary endpoint was the percentage of patients who required a RBV dose reduction. Secondary endpoints included Hb levels, Eprex® dose, and adverse events.

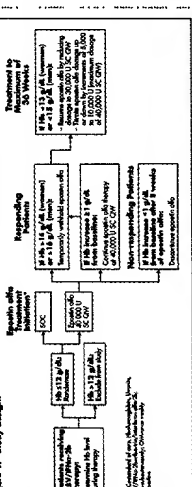
RESULTS

Fifty-four patients were randomized to the Eprex® group and 54 to the placebo group. The Eprex® group had significantly higher Hb levels and fewer RBV dose reductions compared to the placebo group. Eprex® dose was also significantly higher in the Eprex® group.

CONCLUSIONS

Eprex® significantly increases Hb levels and decreases RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy. Eprex® is a safe and effective treatment for anemia in this population.

Figure 1. Study Design



RESULTS

Primary Endpoints: The percentage of patients requiring a RBV dose reduction was significantly lower in the Eprex® group compared to the placebo group (p < 0.05).

Secondary Endpoints: Hb levels were significantly higher in the Eprex® group compared to the placebo group (p < 0.05). Eprex® dose was also significantly higher in the Eprex® group (p < 0.05).

CONCLUSIONS

Eprex® significantly increases Hb levels and decreases RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy. Eprex® is a safe and effective treatment for anemia in this population.

Figure 2. Mean Hemoglobin (Hb) Levels (g/dL) by Treatment Group

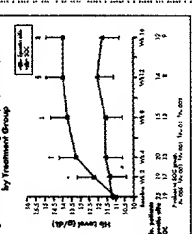
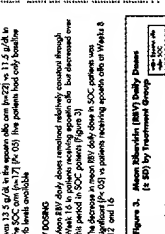


Figure 3. Mean Ribavirin (RBV) Dose (mg/kg/day) by Treatment Group

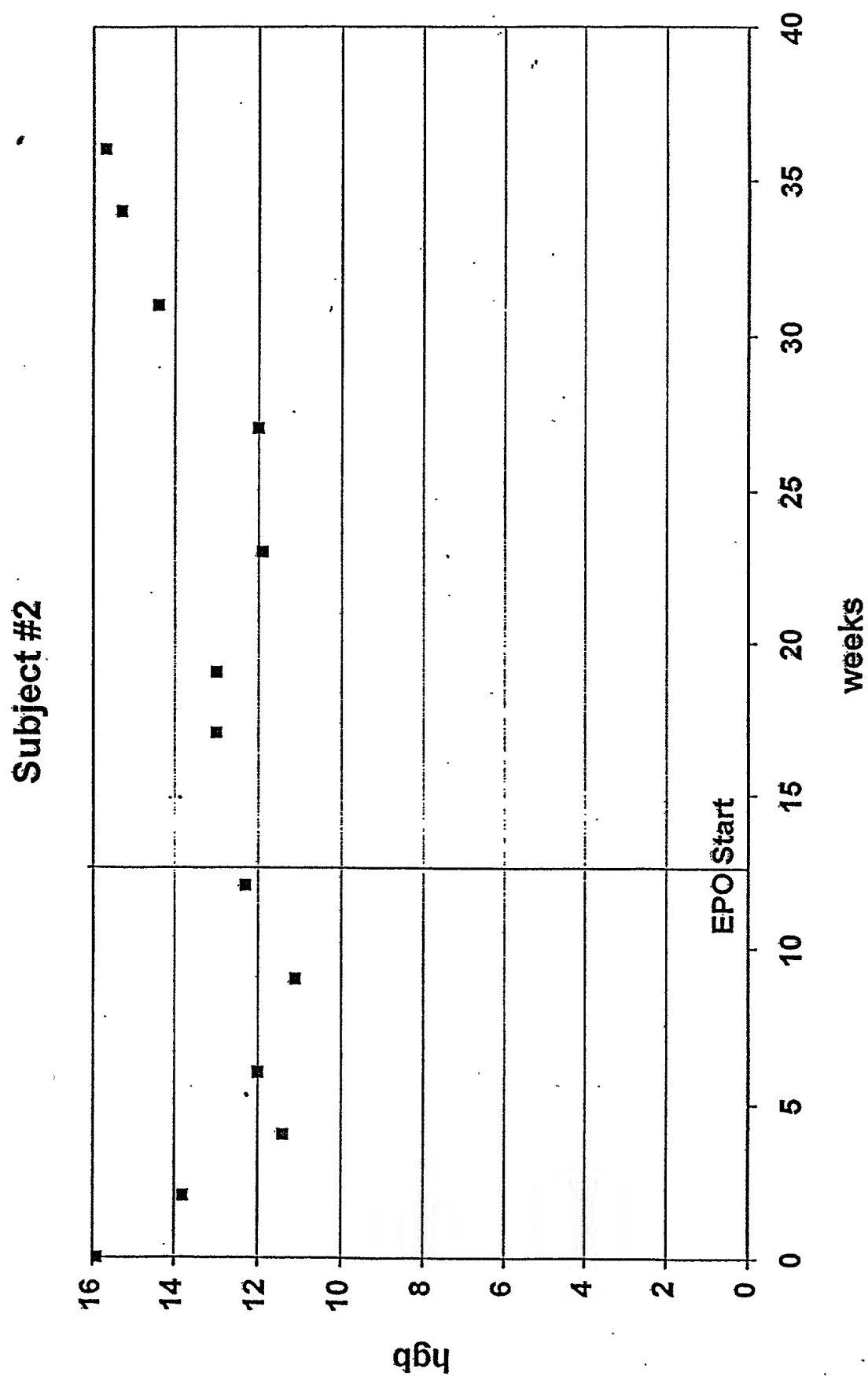


CONCLUSIONS

Eprex® significantly increases Hb levels and decreases RBV dose reductions in HCV-infected patients who develop anemia on RBV therapy. Eprex® is a safe and effective treatment for anemia in this population.

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FIGURE 2.1



Subject #3

FIGURE 2.2

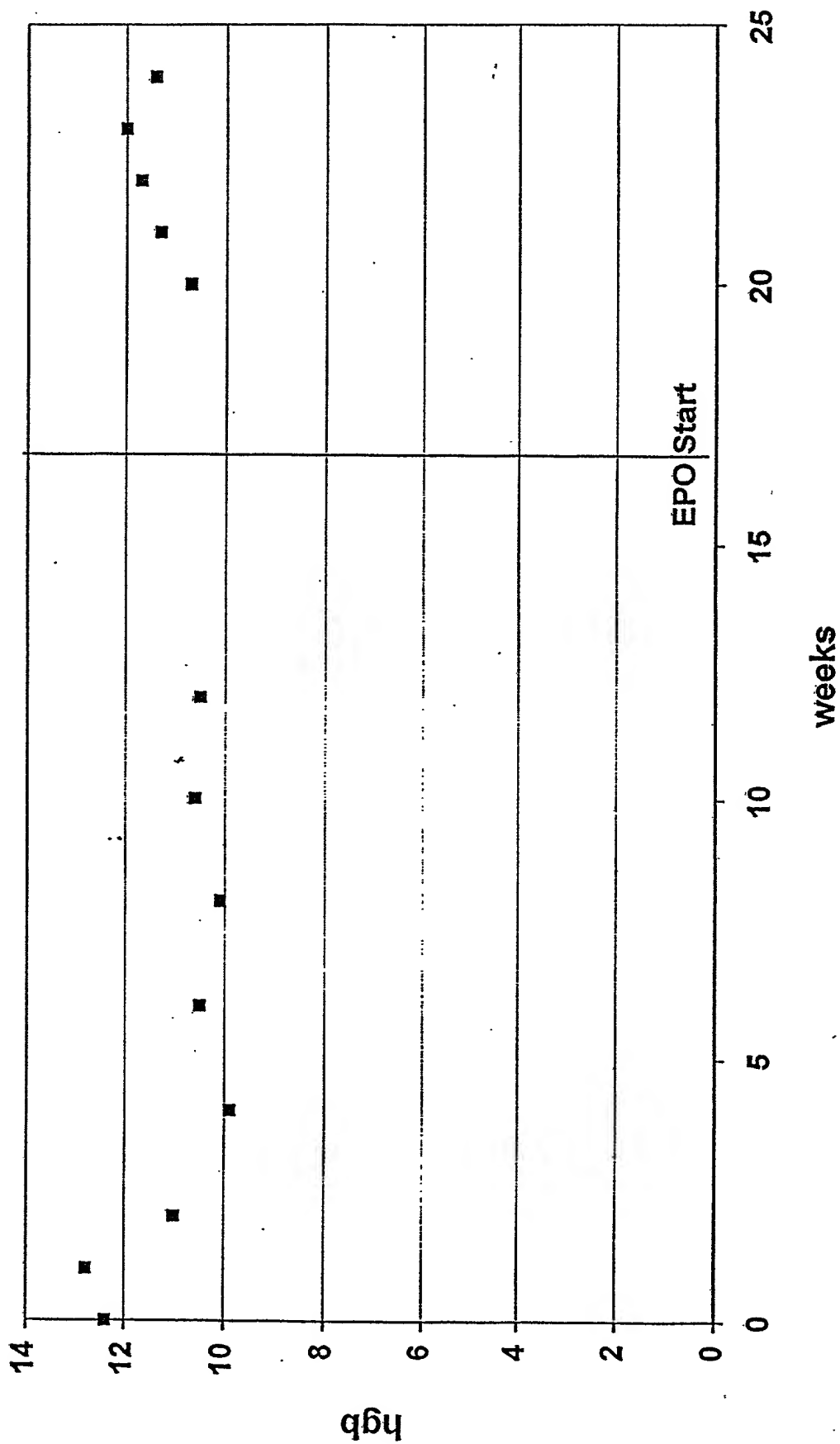
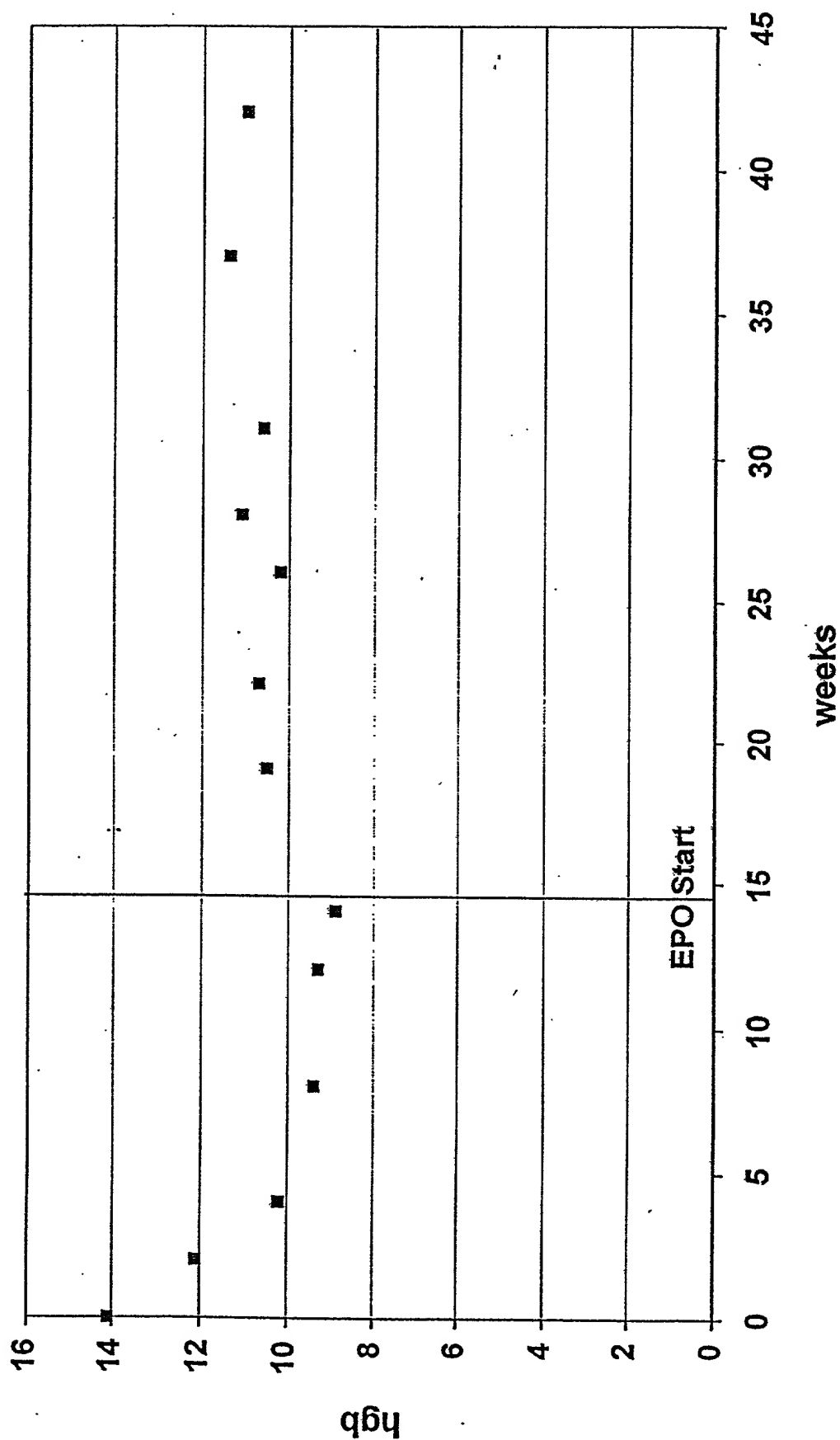


FIGURE 2.3

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Subject #5

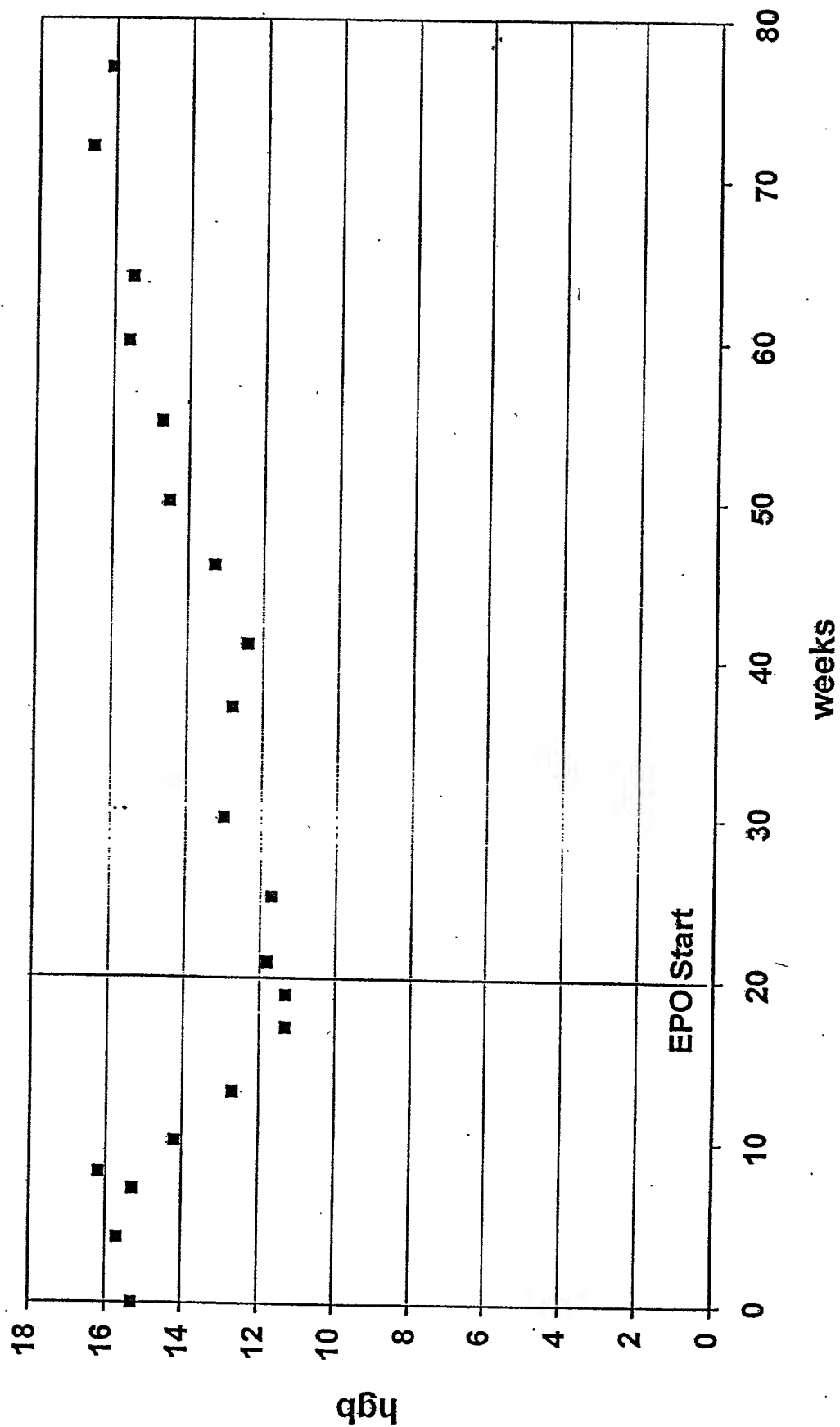
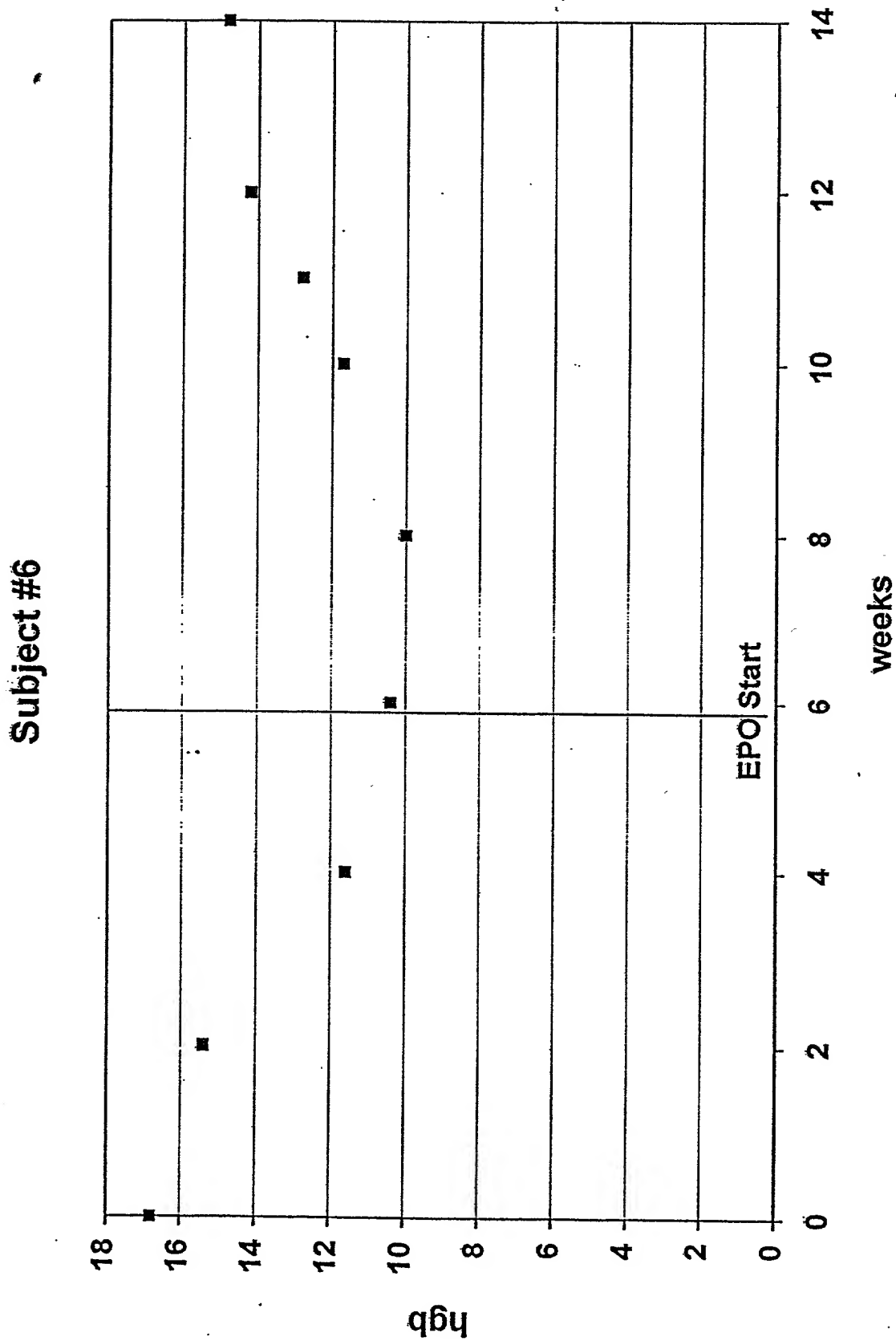


FIGURE 2.4

FIGURE 2.5



Subject #7

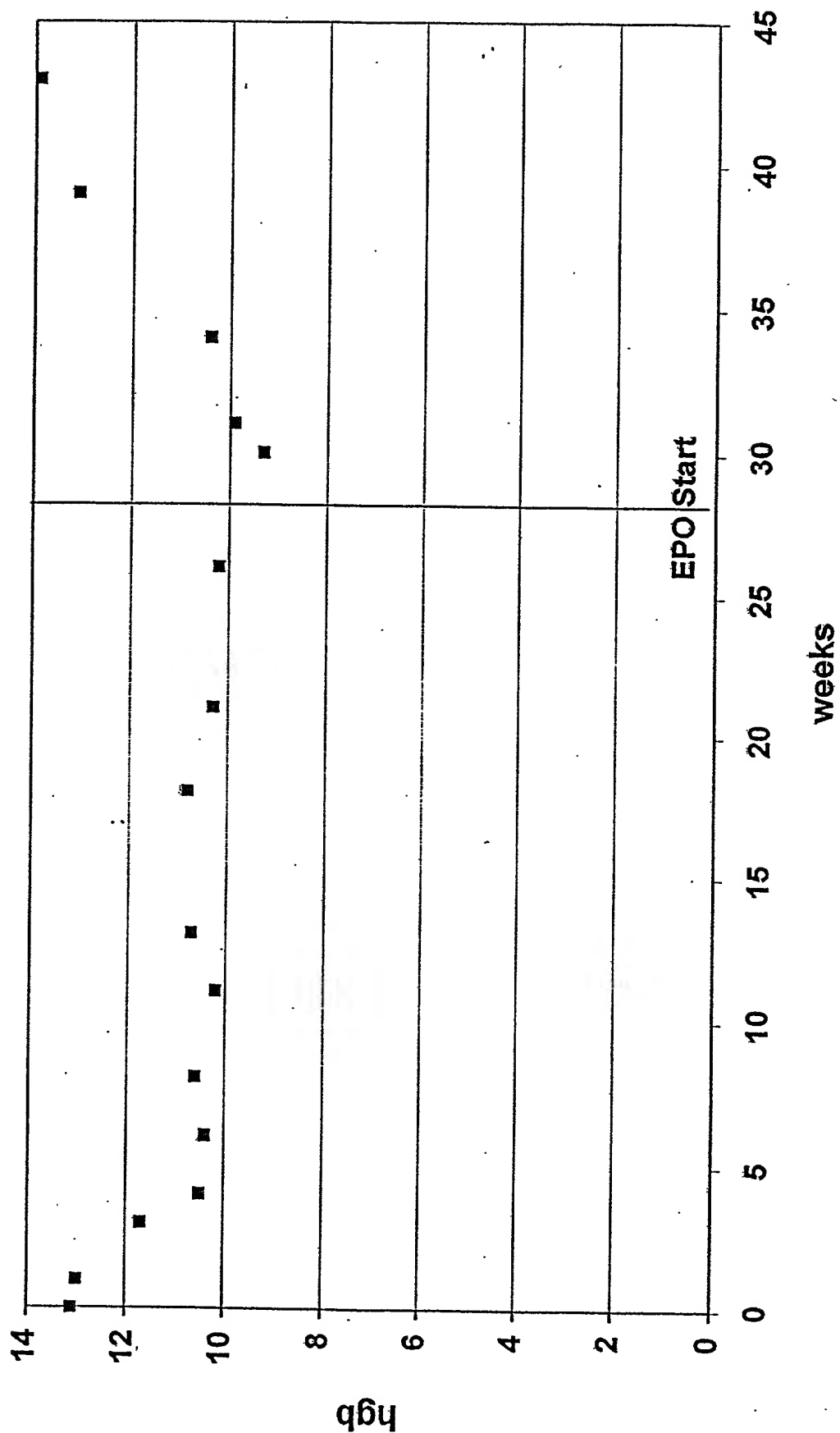


FIGURE 2.6

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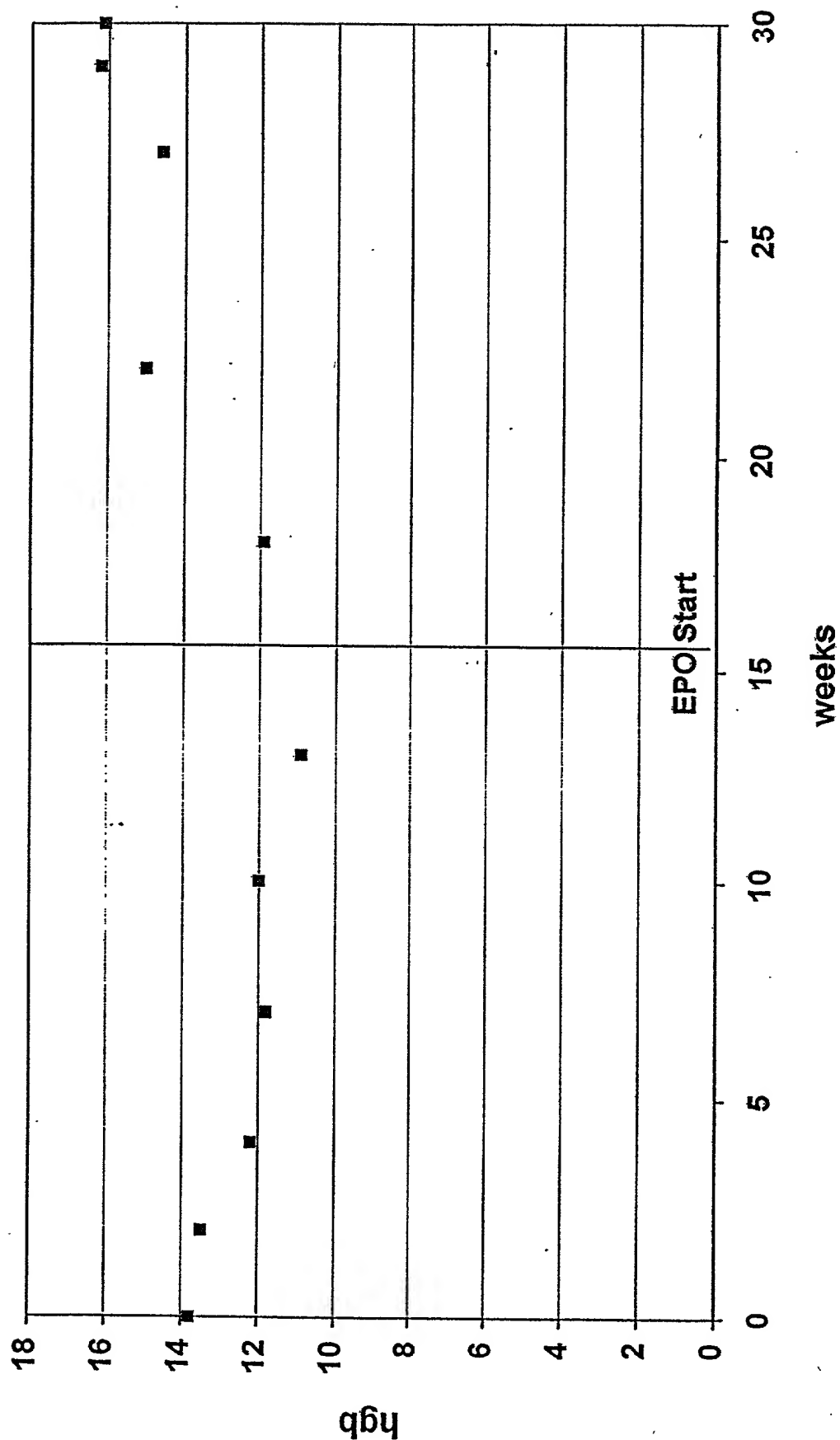


FIGURE 2.7

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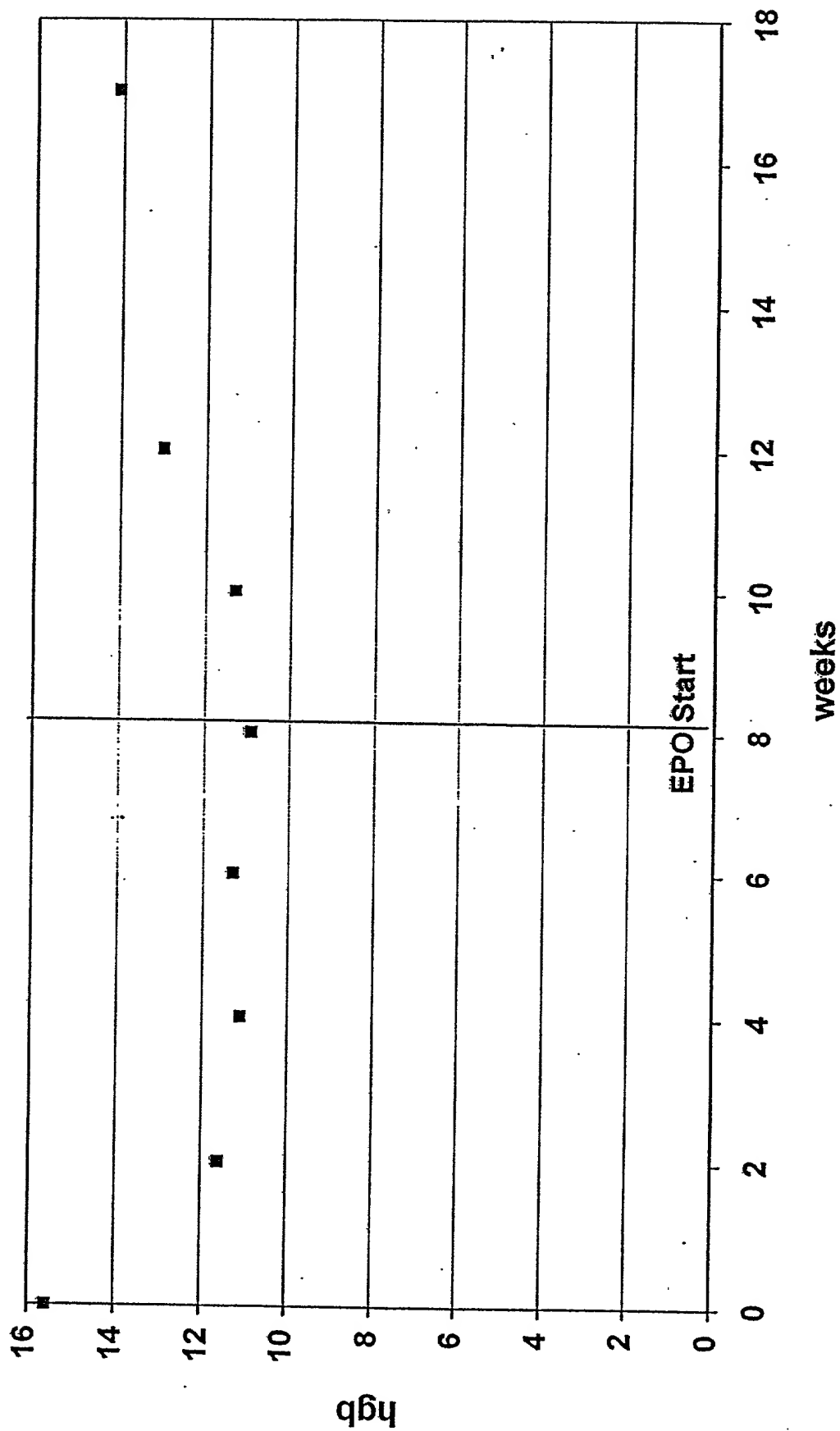
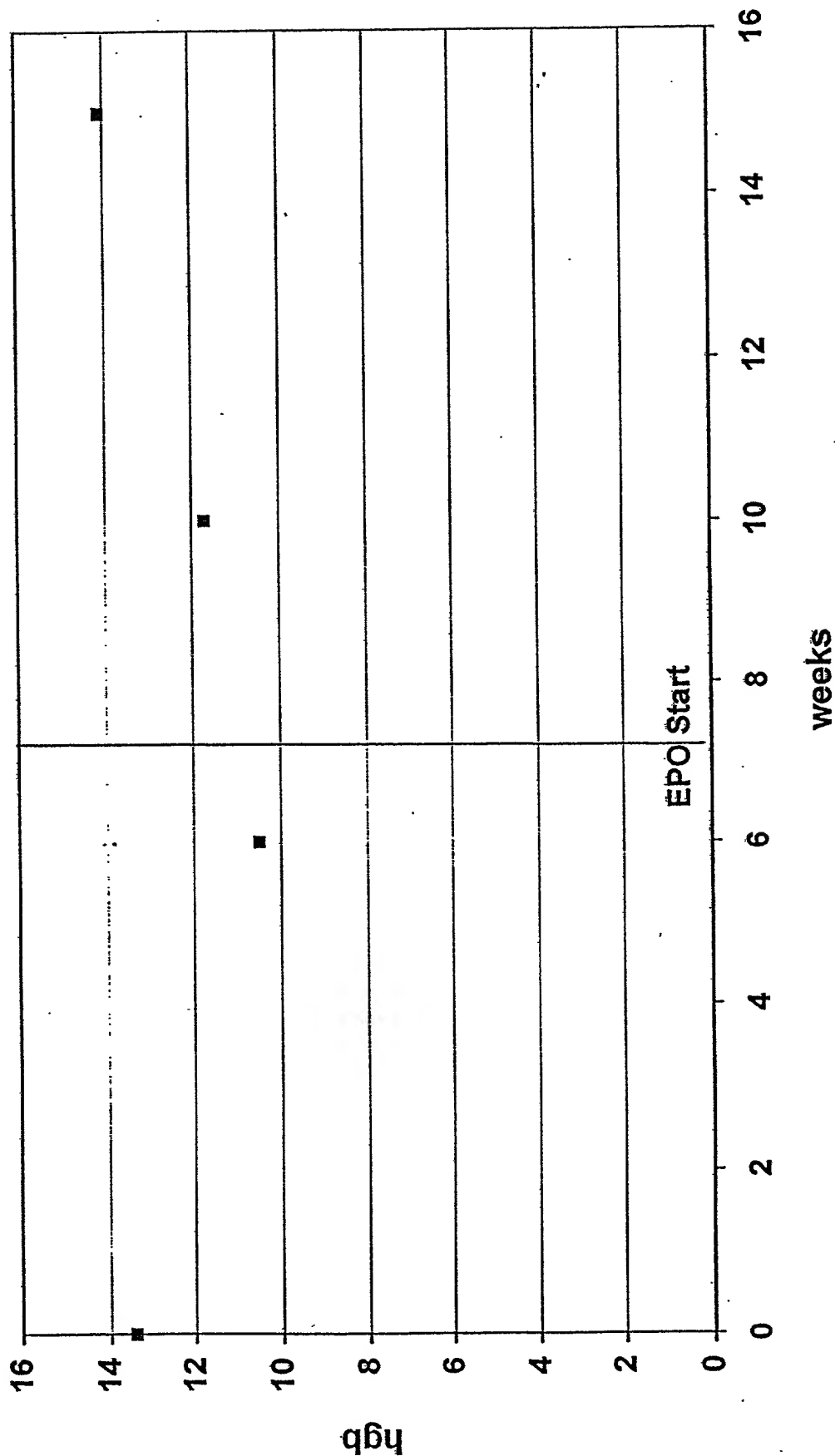


FIGURE 2.8

Subject #13

FIGURE 2.9



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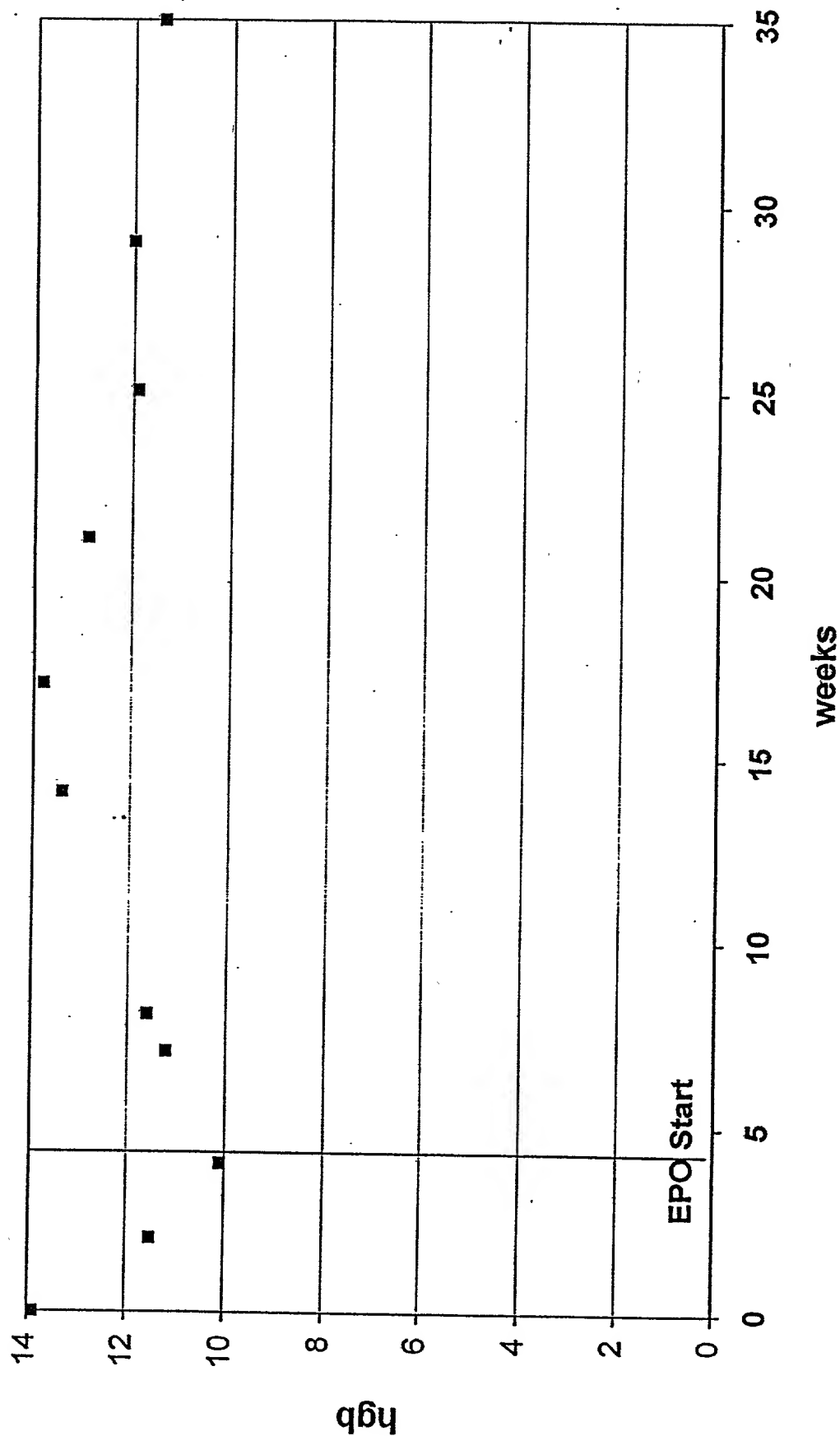


FIGURE 2.10

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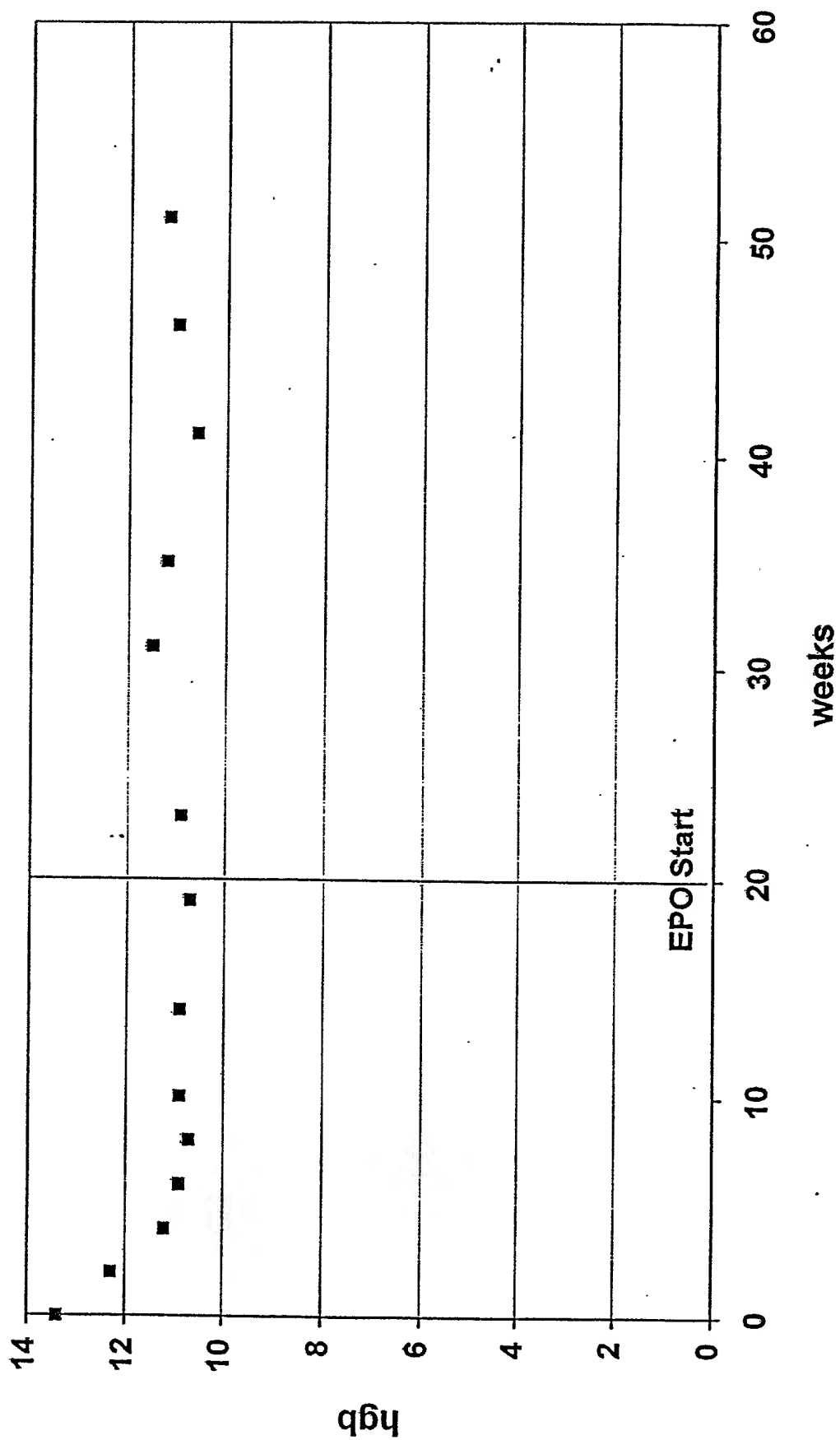


FIGURE 2.11

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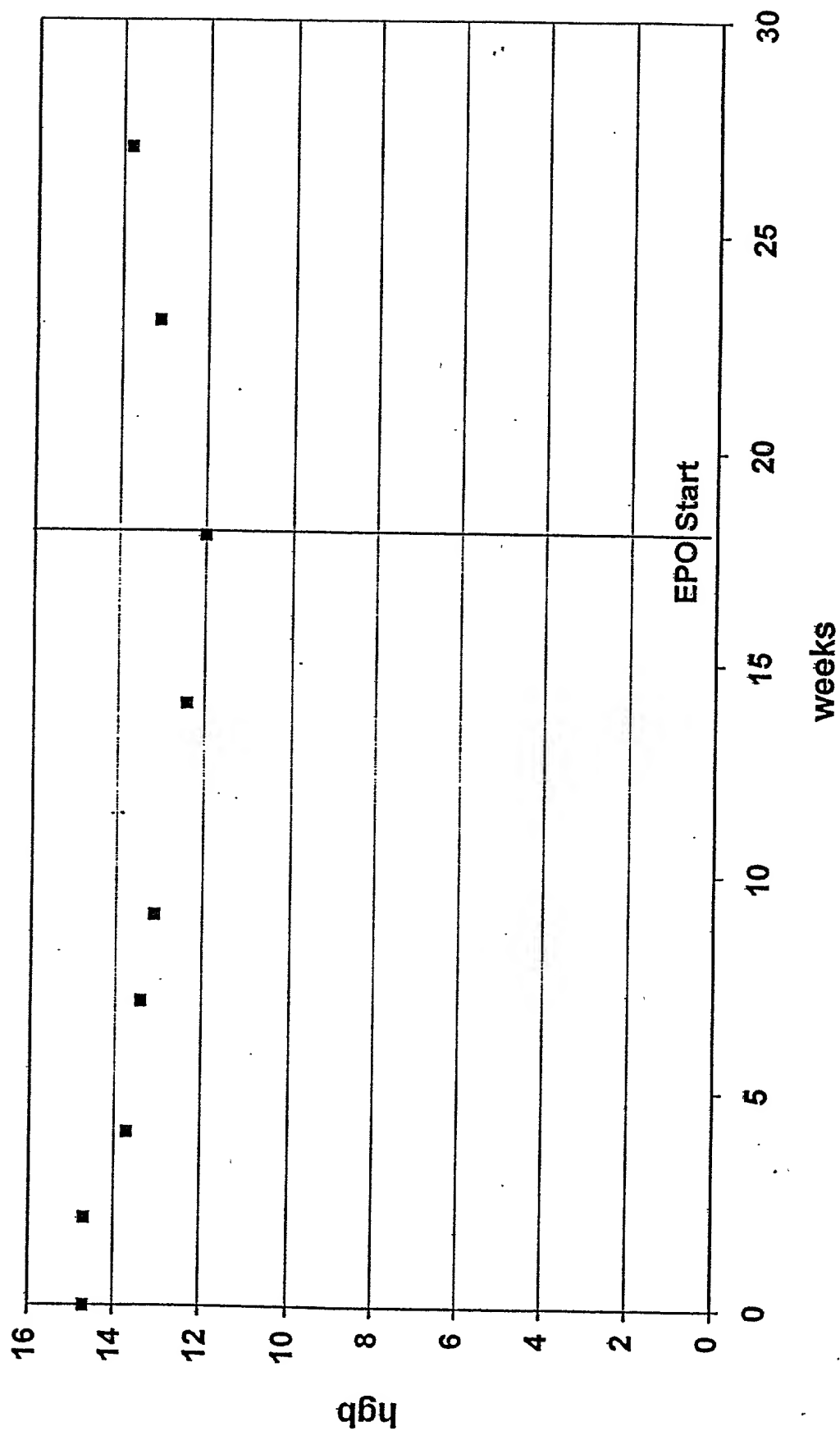


FIGURE 2.12

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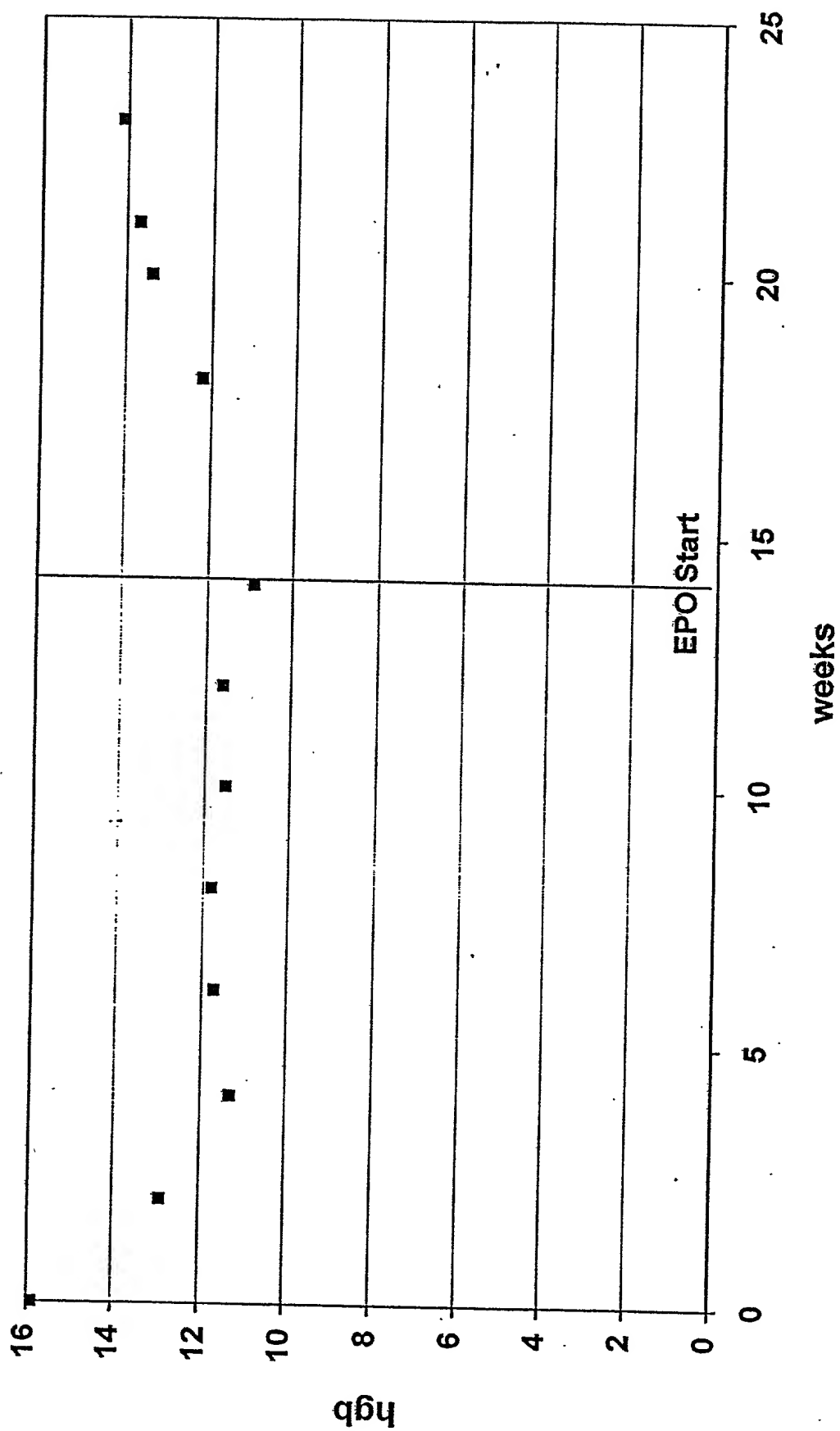


FIGURE 2.13

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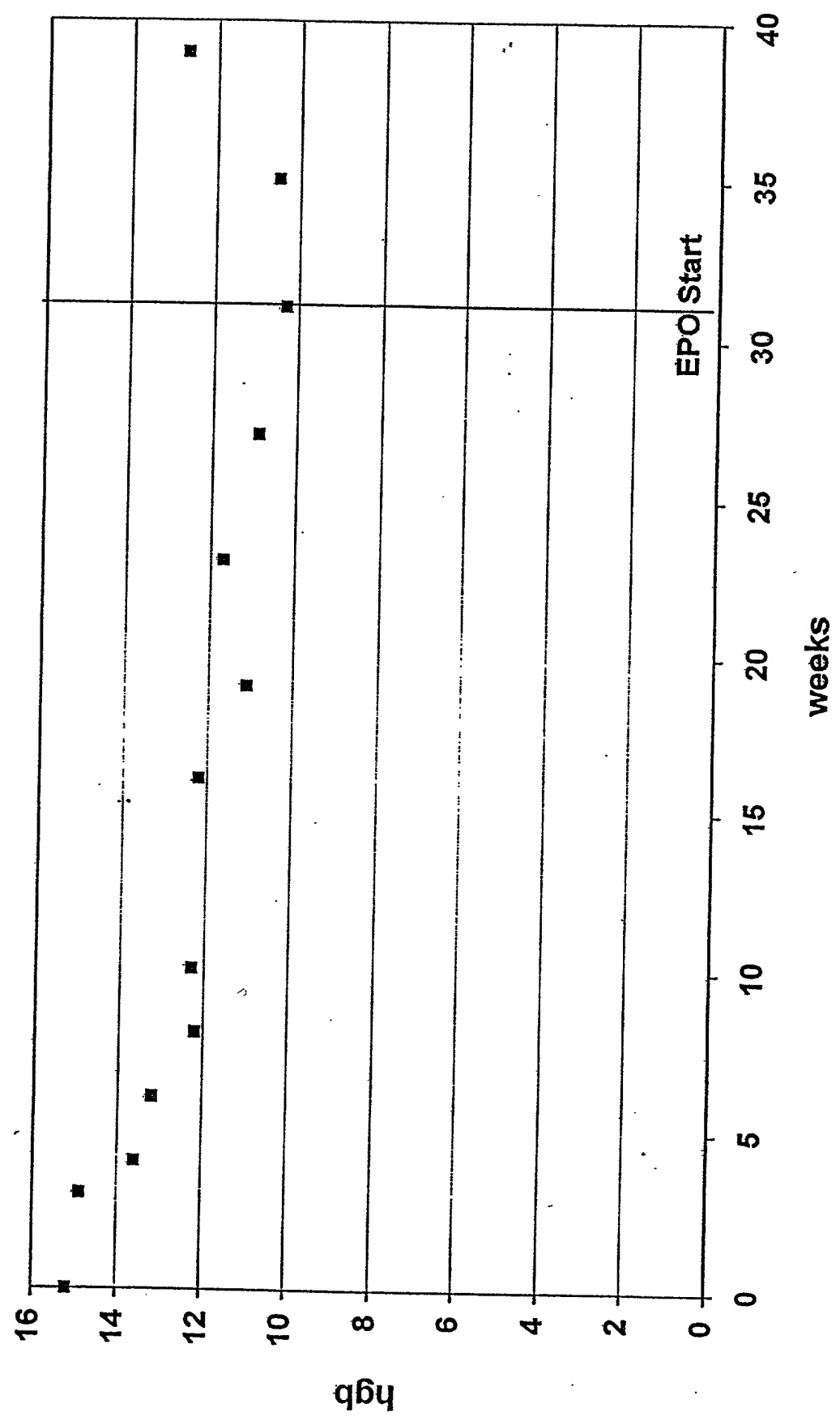
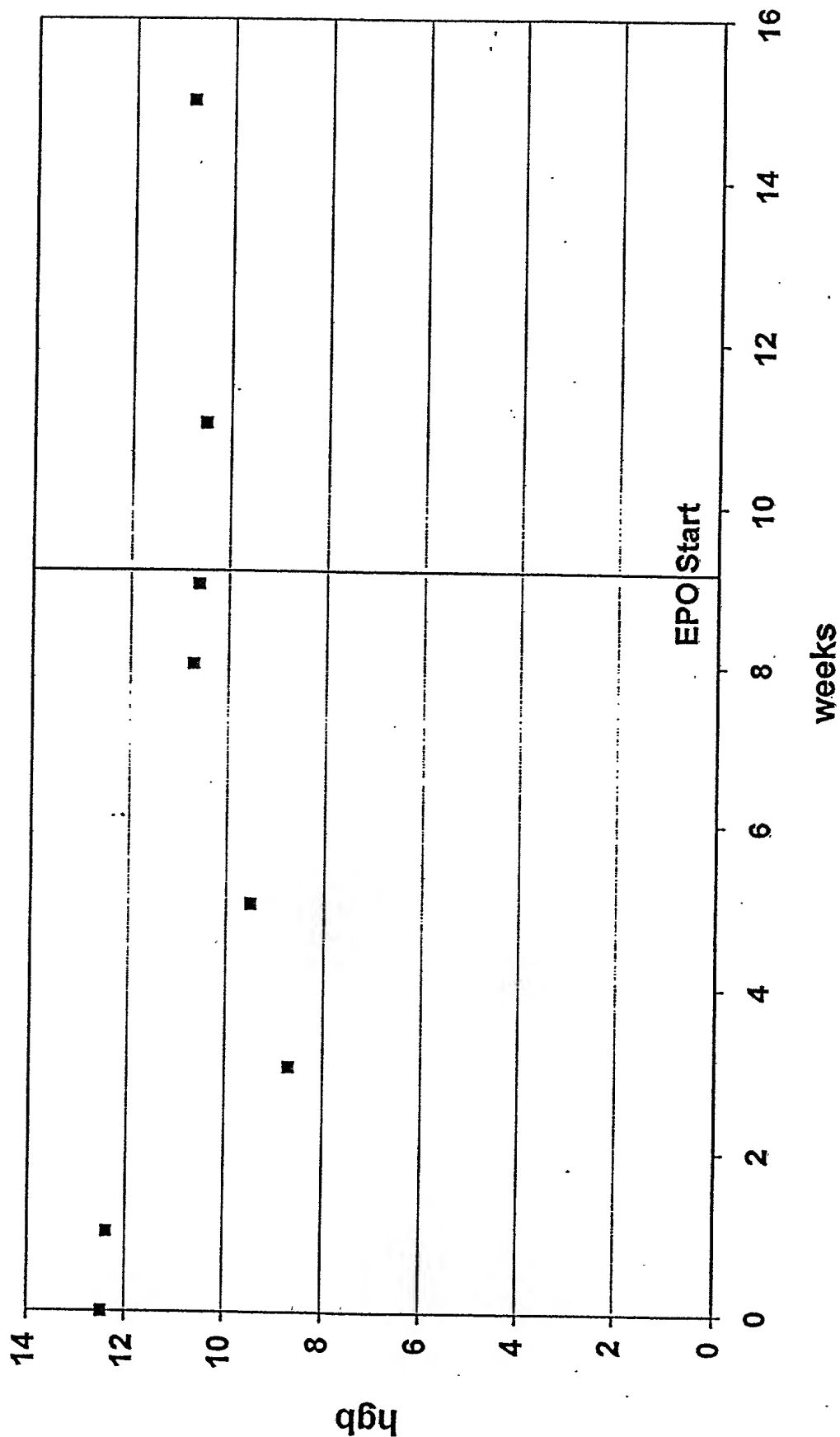


FIGURE 2.14

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FIGURE 2.15



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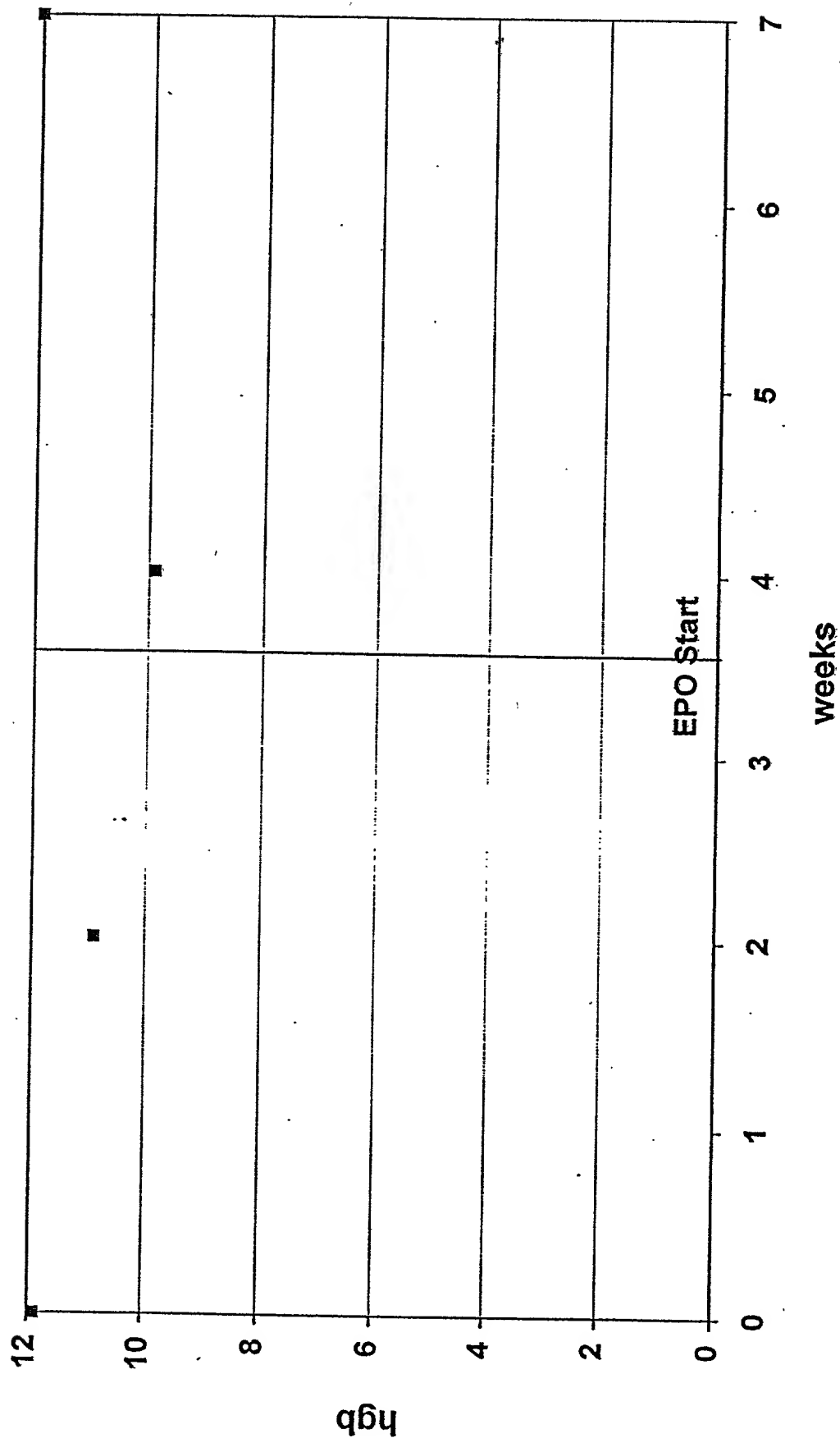
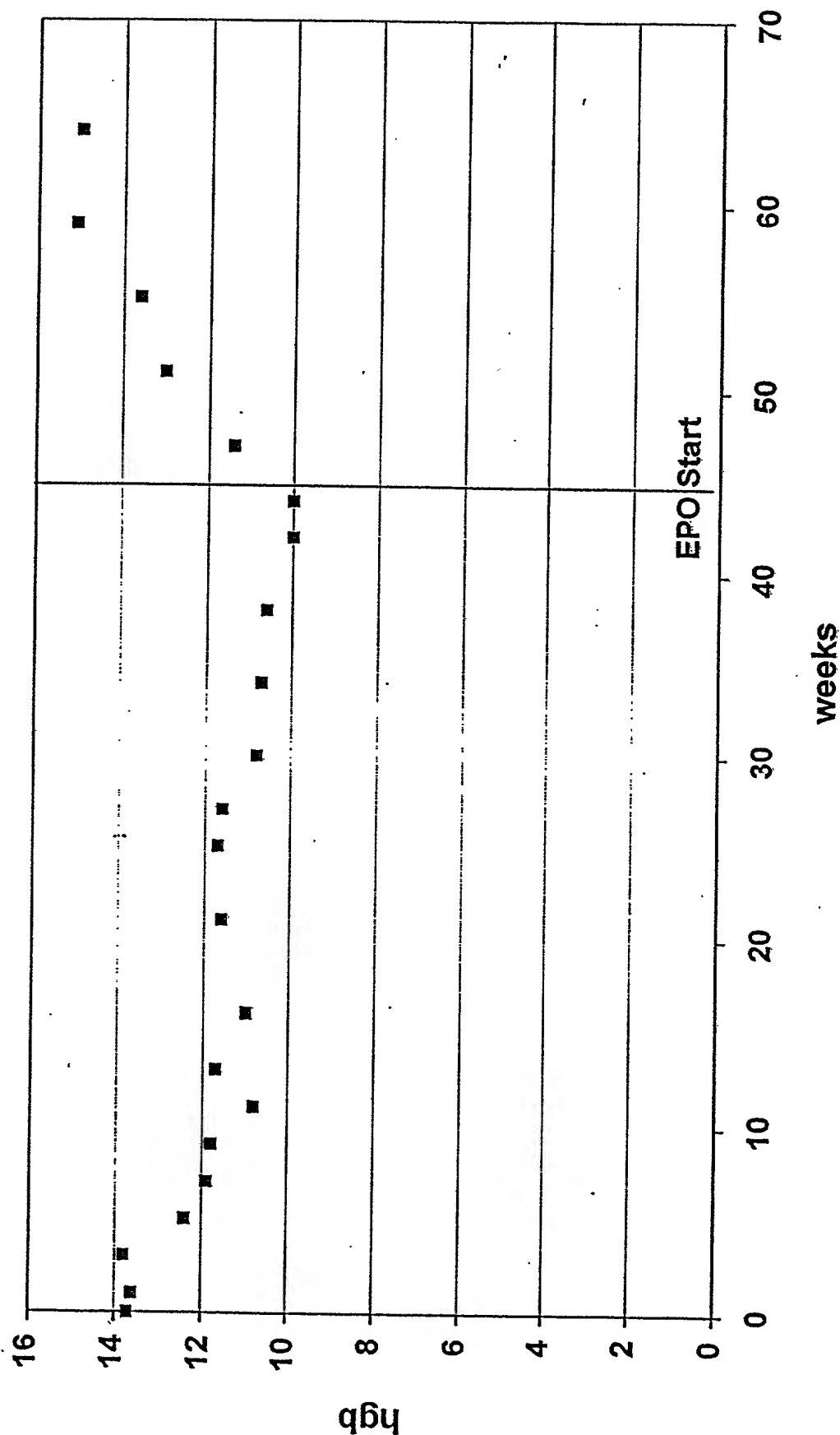


FIGURE 2.16

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FIGURE 2.17



Subject #23

FIGURE 2.18

